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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,149

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Mario Huesca

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NEEDLE & ROSENBERG, P.C.

SUITE 1000

999 PEACHTREE STREET

ATLANTA, GA 30309-3915

EXAMINER

KUDLA, JOSEPH S

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

06/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/579,149

Applicant(s)

HUESCA ET AL.

Examiner

JOSEPH S. KUDLA

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Foreword

1. Applicant's Response to the Election/Restriction correspondence, filed April 28, 2008, is acknowledged. Upon further review of the Election/Restriction correspondence, filed January 28, 2008, the Examiner has determined the Restriction to be improper. Accordingly, the Restriction/Election correspondence, filed January 28, 2008, is rescinded. Applicant is advised that "Use of" claims are not a U.S. statutory class of invention. The Examiner has interpreted the claims as composition claims. Applicant is also advised that improper multiple dependent claims are present and require correction (for example claims 11 and 12).

Below, the Applicant will find the Restriction/Election of Species required before examination of the Application can proceed.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= phenyl;

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and R1= phenyl.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group II, claim(s) 1-27 are drawn to a compound of Formula I;

wherein R2 and/or R3= pyridyl;

and R1= phenyl.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group III, claim(s) 1-27 are drawn to a compound of Formula I;

wherein R2 and/or R3= thiophene;

and R1= phenyl.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group VI, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= biphenyl;
and R1= phenyl.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group V, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= piperidine;
and R1= phenyl.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group VI, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= naphthalene;
and R1= phenyl.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group VII, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and R3= a polycyclic ring system that contains the phenanthroline functional group;
and R1= phenyl.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group VIII, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and R3= a polycyclic ring system that contains the phenanthrene functional group;
and R1= phenyl.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group IX, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and R3= a polycyclic ring system that contains the azulene functional group;
and R1=phenyl.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group X, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= phenyl;
and R1=indole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XI, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= pyridyl;

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and R1= indole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XII, claim(s) 1-27 are drawn to a compound of Formula I;

wherein R2 and/or R3= thiophene;

and R1= indole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XIII, claim(s) 1-27 are drawn to a compound of Formula I;

wherein R2 and/or R3= biphenyl;

and R1= indole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XIV, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= piperidine;
and R1= indole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XV, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= naphthalene;
and R1= indole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XVI, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and R3= a polycyclic ring system that contains the phenanthroline functional group;
and R1= indole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XVII, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and R3= a polycyclic ring system that contains the phenanthrene functional group;
and R1= indole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XVIII, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and R3= a polycyclic ring system that contains the azulene functional group;
and R1= indole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XIX, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= phenyl;
and R1=pyrrole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XX, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= pyridyl;
and R1= pyrrole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XXI, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= thiophene;
and R1= pyrrole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XXII, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= biphenyl;
and R1= pyrrole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XXIII, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and/or R3= piperidine;
and R1= pyrrole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

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Group XXIV, claim(s) 1-27 are drawn to a compound of Formula I;

wherein R2 and/or R3= naphthalene;

and R1= pyrrole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XXV, claim(s) 1-27 are drawn to a compound of Formula I;

wherein R2 and R3= a polycyclic ring system that contains the phenanthroline functional group;

and R1= pyrrole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XXVI, claim(s) 1-27 are drawn to a compound of Formula I;

wherein R2 and R3= a polycyclic ring system that contains the phenanthrene functional group;

and R1= pyrrole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XXVII, claim(s) 1-27 are drawn to a compound of Formula I;
wherein R2 and R3= a polycyclic ring system that contains the azulene functional group;
and R1= pyrrole.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Group XXVIII, claims(s) 1-27 are drawn to a compound of Formula I that are not encompassed by Groups I-XXVII.

A further election of species is required (see below) and this group may be subject to further restriction.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

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Group XXIX, claim(s) 28-38, drawn to a method of treating cancer in a mammal comprising administering a compound of Groups XVI and XVII.

3. The inventions listed as Groups I-XXIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There is no special technical feature in the instant claim set.

Instant claim 1 discloses a compound of formula I where R1=pyrryl, R2 and R3= phenyl and R4=hydrogen. Mjilla (EP 0 812 829 and cited by Applicant) disclose Formula I with the same substituents (page 3, line 35 to page 4, line 40). Therefore, the instant claims do not have a special technical feature and thus the claims lack unity.

Applicant is required to elect a group to be examined on the merits.

Election of Species

Compound

4. Once Applicant elects the group to be examined on the merits, Applicant is then required to elect a species of that group. Claims 1-27 encompass many different compounds that are patentably distinct species, as can be seen in instant claim 6. The compounds depicted in the claims possess different and distinct functionalities and can vary significantly structurally due to the broad number of additional substituents that can be attached to one of the cores listed supra. A search is required of each individual

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species resulting in an unduly extensive search burden. Therefore, Applicant is required to elect a specific compound, to which the elected invention will be examined on the merits as well as to identify those claims to which the elected compound/invention is drawn.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Type of Disorder or Condition

5. If Applicant elects Group XXIX to be examined on the merits, Claims 28-30 are generic due to a plurality of the following disclosed patentably distinct species represented in the instant specification on page 65, line 23 to page 69, line 10. The disorders vary distinctly symptomatically. For example even within cancer, the symptoms associated with breast cancer (e.g. breast pain or lump within the breast) would vary distinctly from the symptoms associated with melanoma (e.g. change in size, shape, color, feel of an existing mole, bleeding from the mole, etc.). Therefore, a subject that has one cancer like breast cancer would not necessarily have the other cancer like melanoma. Thus, an individual search is required of each individual distinct cancer. Applicant is required to elect a disease, like melanoma, from the list on page 65, line 23 to page 69, line 10 to which the elected invention will be examined on the merits as drawn to; as well as identifying those claims to which the elected disease/disorder/condition is drawn.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter.

Additional Anticancer Compound

6. If Applicant elects Group XXIX to be examined on the merits, Applicant is then required to elect a composition with or without an additional anticancer compound. Claim 31 encompasses many different compounds that are patentably distinct species, as can be seen in the instant specification on page 70, lines 9-30. Although all of the compounds are anticancer fighting agents, the compounds depicted in the specification possess different and distinct functionalities. A search is required of each individual species resulting in an unduly extensive search burden. Therefore, Applicant is required to elect a specific compound, to which the elected invention will be examined on the merits as well as to identify those claims to which the elected compound/invention is drawn.

Applicant is cautioned that the election of a species of compound which has not specifically been disclosed as filed may be determined to be New Matter. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that to be complete, the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

7. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph S. Kudla/
Examiner, Art Unit 1611
June 9, 2008

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615